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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/050,249	03/30/1998	HARUKI OKAMURA	OKAMURA=2B	6601

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
01/19/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/050,249	OKAMURA ET AL.	
	Examiner	Art Unit	
	DONG JIANG	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *93,99,100,104,106,107,116 and 121-123* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *93,99,100,104,106,107,116 and 121-123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

The request filed on 02 December 2010 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/050,249 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's amendment filed on 02 December 2010 is acknowledged and entered. Following the amendment, the new claim 123 is added.

Currently, claims 93, 99, 100, 104, 106, 107, 116 and 121-123 are pending and under consideration.

Withdrawal of Objections and Rejections:

The prior art rejection of claim 122 under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al. (Infect. Immun. 61: 64-70, 1993), and further in view of Campbell, A. (Laboratory Techniques in Biochemistry And Molecular Biology, Volume 13, Chapter 1, pages 1-33, 1984) is withdrawn in view of a new ground of rejection (see below).

Rejections under 35 U.S.C. §112:

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claim 122 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While the specification teaches the immobilized monoclonal antibody (pages 53-54), applicants have not pointed out, nor can the Examiner locate, the basis in the specification for the limitation that the immobilized monoclonal antibody is labeled (which also raises the issue of enablement).

This is a new matter rejection.

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 123 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 123 is indefinite for the recitation "i) isolating a mouse liver cell capable of producing said IGIF or said IL-18" because it is unclear how such a cell is isolated. While the specification teaches using the whole mouse liver as a source for producing IGIF, it does not teach isolation of a particular liver cell. The claim is further indefinite for the recitations "culturing said hybridoma … to produce said IGIF or said IL-18 in the culture" (step v)), and "collecting said IGIF or said IL-18 … from the culture" (step vi)) because a hybridoma produces an antibody, not IGIF or IL-18.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 93, 99, 100, 104, 106, 107, 116 and 121 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al. (Infect. Immun. 61: 64-70, 1993), and further in view of Campbell, A. (Laboratory Techniques in Biochemistry And Molecular Biology, Volume 13, Chapter 1, pages 1-33, 1984), for the reasons of record set forth in the previous Office Actions mailed on 2/4/10, and 8/6/10.

Applicants argument filed on 06 October 2010 has been fully considered, but is not deemed persuasive for the reasons below.

At page 3 of the response, the applicant argues that Nakamura clearly states that the cells producing the factor had not yet been identified at the time Nakamura was published, and it is also clear that the source of the gene encoding IGIF was unknown, therefore, it would be impossible even for a skilled person to identify the gene without prior knowledge about the source of the gene. This argument is not persuasive because applicants statement is incorrect as many genes were identified without prior knowledge about the source of the genes, and recombinant technology of gene cloning does not rely on the source of a gene, and this technology was well established and readily available at the time the present invention was filed.

At pages 4-5 of the response, the applicant argues that it is difficult to submit publications which show such negative data, because negative data is not normally published; that Okamura only identified the producing cells two years later is indirect circumstantial evidence that Nakamura or others had repeatedly failed to identify the cells that produce IGIF or the gene encoding IGIF during that two year period; and that Campbell teaches that it would be difficult in practice to obtain a monoclonal antibody without a purified antigen. This argument is not persuasive because applicants have not shown any evidence that the claimed invention satisfies a long-felt need which was recognized, persistent, and not solved by others, and mere argument that the two years is indirect circumstantial evidence that Nakamura or others had repeatedly failed to identify the cells is unsound. Further, more importantly, gene cloning is not dependent on identification of the cell source that expresses the gene. Furthermore, Campbell teaches that it may be true in general that no purification procedures are required (while it may not be true in practice with any specific antigenic mixture). Nakamura's factor was semi-purified, and it was not "any specific antigenic mixture".

Conclusion:

No claim is allowable.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dong Jiang/
Primary Examiner, Art Unit 1646
1/8/11